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14. ABSTRACT: Even though mammography has been proven to be effective in reducing breast cancer mortality this simple screening measure is underutilized by women who are at an inordinately high risk for developing breast cancer. The effect of a reminder telephone call intervention has not been studied in this high-risk population where the need for compliance is crucial. The hypothesis for this study is that a simple reminder telephone call will significantly increase mammography frequency in high-risk women compared to a control group. Four-hundred and forty-seven women consented to participate in the study. Interestingly, 346 (77%) reported obtaining annual mammography for at least the past two years. Subjects who were non-compliant by self-report (n=32) were randomized to the intervention or control group. Reminder and follow-up telephone calls were completed on 31 women randomized to the study. A statistical difference (p=0.0017) was observed between the two groups. These findings support the hypothesis that mammography compliance in high risk women can be increased if an intervention such as a simple reminder call is implemented thereby leading to an early diagnosis and potential cure. Future studies should aim to increase the number of subjects and determine barriers in obtaining mammograms in these high risk individuals.					
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Introduction

Women who are part of a hereditary breast cancer (HBC) family and have a first degree relative with breast or ovarian cancer are potentially at an increased high risk for developing breast cancer as compared to the general population risk. In addition, these high risk women may develop the cancer 10-20 years earlier than the age of onset seen in sporadic breast cancer cases. Women identified as high risk due to family history alone or due to carrying a BRCA1 or BRCA2 genetic mutation are recommended to initial annual mammography starting at the age of twenty-five.

Annual screening mammography is a simple tool that can prove to be life-saving for high-risk women. For women who are known to carry a BRCA1 or BRCA2 genetic mutation, the risk for developing breast cancer approaches 85% by age 70 as compared to the general population risk of 11%. According to Burke, et. al. (1997) options afforded to these high risk women include surveillance measures, prophylactic bilateral mastectomy, or chemoprevention for early detection and prevention. For women who opt to undergo heightened breast cancer screening, annual mammography is recommended starting at age 25 in concert with monthly self-breast examination and bi-annual clinical breast examination according to Lynch, et. al. (2003). Unfortunately, the rate of annual mammography screening is suboptimal as reported by Tinley, et. al. (2004) and Peshkin et. al. (2002). In addition, Issacs, et. al. (2002) reported that “prior to obtaining genetic counseling or testing, 50% of high risk women ages 30-39, 83% of those age 40-49, 69% of those 50-64, and 53% of those >65 reported having a mammogram in the prior year.” These findings support the need for effective interventions to increase mammography compliance in high risk women.

The hypothesis of this study is that a simple reminder telephone call will increase mammography compliance in women who have been identified as being at high risk due to their family history or BRCA1/2 genetic carrier status. This is a randomized prospective study in which recruited women were assigned to an intervention group wherein they received a reminder telephone call 1-2 months before their mammogram was due or to a control group wherein they did not receive a reminder telephone call prior to when their mammogram was due. All women received a follow-up call 1-2 months after their mammogram was due to determine if they indeed had received a mammogram. A subgroup of women was randomly selected to confirm the self report of obtaining a mammogram.

Body

Women who are part of a HBC family and have a first-degree relative with breast or ovarian cancer are at a high risk for developing breast cancer. Therefore, it is vital these women adhere to the recommended screening measures, inclusive of annual mammography beginning at age twenty-five. It is hypothesized that a simple reminder telephone call from a receptionist will promote increased compliance in mammography among these women.

Methods

One-thousand and eighty-five women registered in the Breast Cancer Resource at Creighton University, Hereditary Cancer Center were identified as being eligible for the study and were therefore invited to participate in this research study. See Appendix A for Study Flowchart. Four-hundred and forty-seven (41.2%) responded and 638 (58.8%) did not respond. Of the 447 women who responded, 346 (77.4%) reported that they were already compliant with annual mammography and had been for at least the past two years. Only 32 (7%) women who responded reported that they were not compliant with annual mammography. Therefore, these 32 women were randomized to either the intervention or

control group. Sixty-nine (15%) of the women who responded declined participation in the study. Thirty of these women who declined did not provide a specific reason, 16 had underwent a prophylactic bilateral mastectomy, 6 had developed breast cancer, and 7 did not have health insurance to cover the annual mammogram.

Reminder and follow-up telephone calls have been completed on 31 women randomized to the study. One women assigned to the control group has not responded to phone messages or letters to indicate if she had received a mammogram at the designated month.

Statistical Analysis

Utilizing the Fisher's Exact test through www.exactoid.com/fisher/index.php, a comparative analysis was conducted on the two groups for insurance coverage, education level, household income level and employment status. Current ages for both groups were compared as well through a t-test with Microsoft Office XP Excel program.

The comparative statistic results demonstrated that the two groups were comparable in terms of age ($p < 0.77$) with a mean of 46.8 years, insurance coverage ($p = 1$), education level ($p < 0.16$), household income level ($p < 0.68$) and employment status ($p < 0.12$).

Of the experimental group ($n=14$) twelve women received their annual screening mammogram (86%) and 2 (14%) did not. Of the control group ($n=17$) 5 women received their annual screening mammogram (29%) and 12 women (71%) did not. A Chi square value of $p=0.0017$ was found. Therefore, the hypothesis of this study was supported. A simple reminder telephone call can increase the compliance of annual mammography in high risk women.

Tasks as described in the approved statement of work have been completed except for the submission of a manuscript. It is the PI's goal to submit a manuscript to the Oncology Nursing Forum or to Familial Cancer this year.

- Task 1: Development of Study Tracking, Months 1-2
 - a. A tracking system in Excel has been created to track all subjects who were invited to participate in the study.
 - b. All eligible subjects were identified from the Hereditary Cancer Institute database.
 - c. A separate excel spreadsheet was developed to track the randomized subjects as to their mammogram due month so that a schedule of reminder and follow-up telephone calls can be followed.
 - d. A consent form and Healthcare Insurance Portability and Accountability (HIPAA) forms were developed according to institutional and federal regulations.
 - e. An invitation letter was developed which provided a brief description of the study.
 - f. Institutional Review Board (IRB) approval was obtained for the study, consent and HIPAA form.
 - g. Training of the research assistant was conducted so that reminder and follow-up telephone calls are conducted in a consistent and accurate manner.
- Task 2: Recruitment of Eligible Subjects, Months 2-5
 - a. All eligible women were invited to participate and were mailed an invitation letter, our IRB approved consent form and HIPAA form along with the Pre-Intervention Assessment (PIA) questionnaire.

- b. Follow-up letters were mailed to 778 individuals who did not respond to the initial invitation letter. When an adequate number of responses were received, it was noted that the majority of the women consenting to participate already reported themselves as being compliant with annual mammography for at least the past two years. Therefore, only non-compliant women were randomized to the study. Approval for this change in protocol change was obtained from the Department of Defense.
 - c. Another Excel spreadsheet was developed to enter all of the PIA information on the subjects who responded to the invitation letter.
 - d. As mentioned in 2b, only women who stated that they were not compliant with annual mammography for at least the past two years (n=32) were randomized to either the intervention or control group.
 - e. A schedule was established in Excel as to when each subject randomized to the study would receive their reminder and/or follow-up telephone calls.
- Task 3: Conduct Scheduled Reminder and Follow-Up Calls, Months 5-22
 - a. Reminder telephone calls have been conducted as scheduled. To date, 31 of the 32 women have received a reminder and/or follow-up telephone call. One woman in the control group was lost to contact and has not responded to telephone messages nor letters.
 - b. Follow-up telephone calls have been conducted as scheduled for women in the intervention and control groups. One woman in the control group has not been reached to determine if she had received a mammogram in the scheduled month. The research assistant has continued to try and reach her by leaving phone messages and by letter. The PI has also attempted to reach the subject but was unsuccessful.
 - c. The PI has continually monitored the research assistant and data entry for the study. Both the research assistant and data entry person have come to the PI for questions and clarification throughout the study, which were addressed and resolved.
 - d. Medical authorization on all 32 subjects was obtained at the same time they had consented to be part of the study.
 - e. Eight of the 17 women who obtained a mammogram were randomly selected to confirm their self report of obtaining a mammogram. A confirmation of obtaining a mammogram when self reported was obtained on all 8 subjects. Four women were selected for each of the two groups.
 - f. A final report is written and submitted.
- Task 4: Final Analysis and Report Writing, Months 23-26:
 - a. A final analysis has been conducted and findings are reported above and in the Key Research Accomplishments section.
 - b. A final report has been written and submitted.
 - c. Manuscript preparation has started but not yet completed to the point of submitting it to a journal. It is the PI's goal to submit the completed manuscript to the Oncology Nursing Forum and/or to Familial Cancer for publication.

Overall there was no difficulty in accomplishing the tasks outlined above. However, the number of eligible women to randomize to the study was disappointing due to the high number of women who reported themselves as compliant to mammography compared to those who were non-compliant. The findings would be more significant if the number of subjects randomized to the two groups could be increased significantly. Recruiting women who are non-compliant with mammography may be difficult. However, seeking collaboration with other centers may increase the number of subjects significantly.

In future studies tailored reminder telephone calls may be beneficial in moving high-risk women who are non-compliant to become compliant. In addition, barriers to mammography compliance need to be explored in more depth. According to Tinley, et. al. (2004) physician's behavior towards screening measures, inclusive of mammography significantly affected women's decisions to have an annual mammogram.

Key Research Accomplishments

- A statistically significant result of the intervention of a simple reminder call on increasing mammography compliance in high risk women was found between the control and experimental group.
- A significant number (77%) of the high risk women who responded reported themselves as being compliant with annual screening mammography for the past two years.
- The need to increase collaboration between multiple centers was identified in order to obtain a significant number of subjects to determine the effectiveness of a reminder telephone call intervention since the numbers in this current study were small.

Reportable Outcomes

- Poster presentation at the International Society of Nurses in Genetics Annual Conference held October 23-26, 2004 in Toronto, Canada. (Appendix B)
- Poster presentation at the Era of Hope 2005, Department of Defense held June 8-June 11, 2005 in Philadelphia, PA. (Appendix C)
- Poster presentation to the School of Nursing at Creighton University, Omaha, NE on August 8, 2006.
- Through the support of this grant the PI has obtained a Masters of Science in Nursing degree with an Adult Clinical Nurse Specialist track with a focus in adult oncology.

Conclusion

Women who are determined to be at high risk for developing breast cancer whether it be due to their family history alone or due to carrying a deleterious BRCA1 or BRCA2 genetic mutation need to adhere to annual screening mammography to detect a breast tumor at an early stage. Unfortunately, the compliance rate of annual mammography among high risk women is not ideal and can and should be improved. Interventions such as reminder telephone calls and mailed reminder postcards have been utilized to increase mammography compliance. Taplin, et al (2000) reported that women who received a reminder call were more likely to get mammograms (HR = 1.9; 95% CI = 1.6-2.4) than women who received reminder postcards. Taplin also compared the effect of a more complex motivational call compared to a simple reminder call. It was determined a simple reminder call was just as effective as a more time-consuming motivational call. This study used a simple reminder telephone call as the intervention to increase mammography compliance. This intervention was found to significantly (p=0.0027) increase mammography compliance in high risk women.

These findings are significant for advanced practice nurses who work in a breast cancer center or in cancer centers and wish to increase compliance with annual mammography. This study was purposefully designed to replicate a clinic setting wherein a receptionist could conduct the reminder telephone call to women who are due for an annual mammogram. An advanced practice nurse could develop and oversee this process and intervene with those high risk women who do not respond to the simple intervention. An advanced practice nurses' time would be better utilized by focusing on those women who need additional motivation, support or education regarding the benefits of mammography.

This study has provided the PI with extremely valuable experience and skills in conducting a randomized study. Through the guidance and mentorship of Drs. Henry Lynch and Patrice Watson the PI has gained invaluable knowledge and experience. The statistical analysis on the data provided in the study was conducted by the PI and then reviewed by Dr. Watson. Since the simple intervention of a reminder telephone was determined to significantly increase mammography compliance in high-risk women this intervention may be considered to be used in breast cancer and high risk clinics thereby increasing the number of breast cancers detected at an early stage and then hopefully cured. However, since the number of subjects was small future studies should strive to increase the number of subjects and consider the use of a tailored telephone call to encourage women to obtain a mammogram by working through the barriers they may be experiencing.

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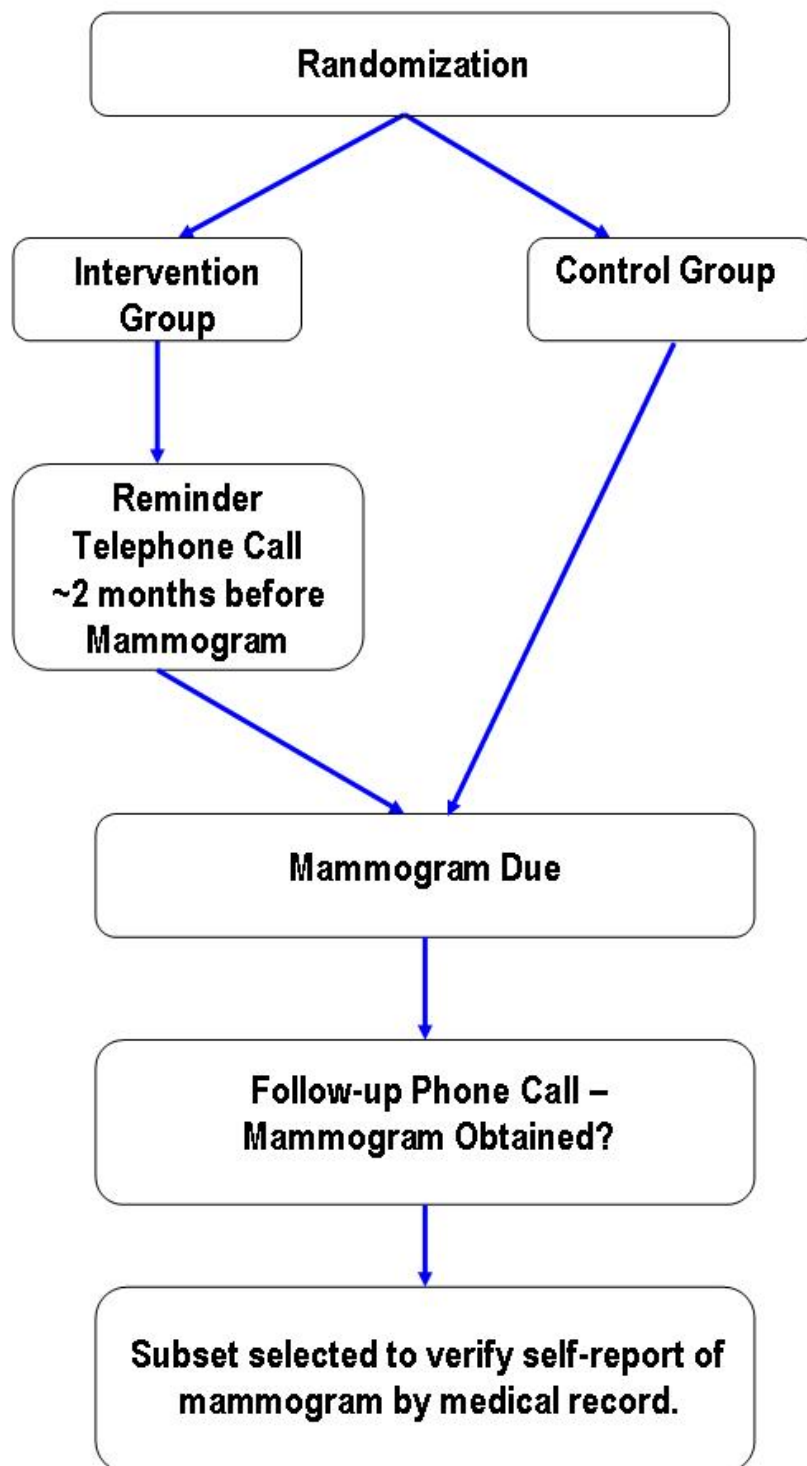
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1. Poster presentation at the International Society of Nurses in Genetics Annual Conference held on October 23-26, 2004 in Toronto, Canada. *Effect of Reminder Telephone Call on Mammography Compliance in High-Risk Women*
2. Poster presentation at the Era of Hope 2005, Department of Defense held on June 8-11, 2005 in Philadelphia, PA. *Effect of Reminder Telephone Call on Mammography Compliance in High-Risk Women*
3. Poster presentation at the School of Nursing at Creighton University, Omaha, NE on August 8, 2006. *Effect of Reminder Telephone Call on Mammography Compliance in High-Risk Women.*

Personnel Supported by Grant

1. Carrie Snyder, Principal Investigator
2. Deborah Barnard, Research Assistant
3. Sherry Kincaid, Data Entry

Appendix A: Study Flowchart



EFFECT OF REMINDER TELEPHONE CALLS ON MAMMOGRAPHY COMPLIANCE IN HIGH-RISK WOMEN

Carrie Snyder, RN, BSN, OCN

Department of Preventive Medicine, Creighton University Medical Center

ABSTRACT

Even though mammography has been proven to be effective in reducing breast cancer mortality this simple screening measure is underutilized by women in the general population as well as by women who are high-risk. The purpose of this randomized prospective study is to determine the effect of a simple reminder telephone call on mammography compliance in high-risk women. Evidence from eight of nine reviewed research studies conducted on women in the general population reported a significant increase in mammography compliance after a reminder telephone call was implemented. Women identified as being at high risk due to family history or the presence of a BRCA1 or BRCA2 genetic mutation are recommended to have annual mammography beginning at age 25 since their breast cancer risk approaches 85% and the cancer occurs much earlier. A reminder telephone call intervention has not been conducted in this high-risk population where the need for compliance is crucial. The hypothesis for this study is that a simple reminder telephone call will significantly increase mammography frequency in high-risk women compared to a control group. Subjects will be recruited from Creighton University's Hereditary Breast Cancer Resource of 472 families identified with hereditary breast ovarian cancer. Women who are at least 25 years old and have a first-degree relative diagnosed with breast or ovarian cancer will be invited to participate. A reminder telephone call will be conducted two months prior to the due month for mammography for women in the intervention group. Women in both groups will receive a follow-up telephone call two months after their reported due month for mammography. A Chi-square analysis will determine the effectiveness of reminder telephone calls in high-risk women. The implementation of a simple reminder telephone call may be conducted by advanced practice nurses working with high-risk women in order to increase mammography compliance thereby contributing to early detection and the best chance for a cure.

BACKGROUND

Women who are part of a family with a hereditary breast ovarian cancer pattern and have a first degree relative with breast or ovarian cancer are at an increased risk for developing breast cancer 10-20 years earlier than women without a family history. It is vital these high-risk women follow the recommended screening measures of monthly self-breast examination, bi-annual clinical breast examination, and annual mammography. Even though mammography has been proven to decrease mortality and morbidity, women in the general population as well as high-risk women are still underutilizing it for early detection. Several intervention studies have been conducted in the general population to increase mammography compliance. Reminder telephone calls were found to be effective in those studies in increasing mammography compliance in women who are at the general population risk of 12%.

HYPOTHESIS

The hypothesis for this study is a simple reminder telephone call will increase mammography frequency in high-risk women compared to a control group of high-risk women who will not receive a reminder telephone call.

SPECIFIC AIMS

The specific aims of this study are 1) to determine the effect of a reminder telephone call on mammography compliance in high-risk women and 2) to train the candidate through mentoring and interdisciplinary collaboration how to conduct and analyze the findings of a randomized clinical research study to further her career in breast cancer research.

PRE-INTERVENTION ASSESSMENT

Office Use: ID#: _____

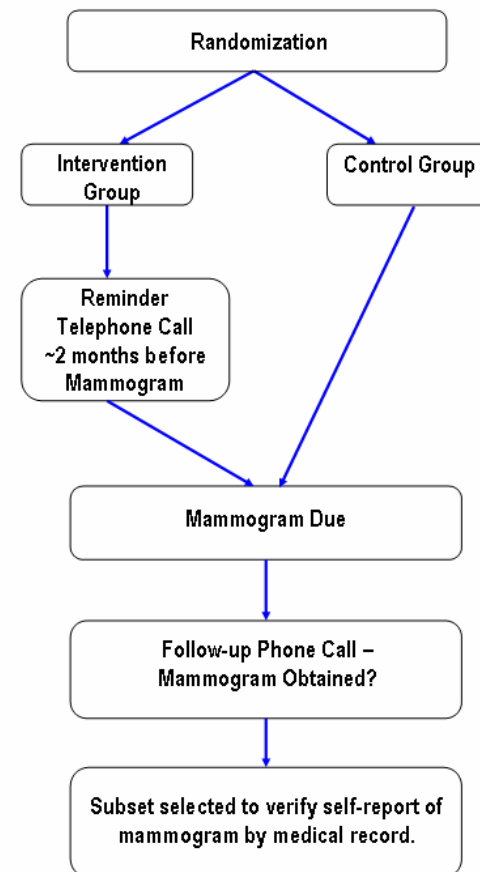
Pre-Intervention Assessment (PIA) Questionnaire

- Have you ever had a mammogram? Yes No
If you answered Yes:
• how many have you had over the past 2 years? _____
• what month of the year are they routinely due? _____
If you answered No:
• do you plan to start having mammograms? Yes No
• if so, which month would you routinely have them done? _____
(Please indicate a month in order to be enrolled into the study.)
- Have you ever had breast cancer? Yes No
- Have you had one or both of your breasts removed either for cancer or for prevention? Yes No
- Do you have health insurance? Yes No
- Are you currently employed? Yes No
Is Yes: Full-time? Part-time? (Please circle one.)
- What best indicates your household income before taxes last year? (Optional)
☐ less than \$20,000 ☐ \$50,001 - \$75,000
☐ \$20,001 - \$35,000 ☐ over \$75,000
☐ \$35,001 - \$50,000
- How much education have you completed?
☐ less than high school graduate ☐ college graduate
☐ high school graduate ☐ professional or postgraduate degree
☐ trade school or some college
- Race (please check all that apply) Ethnicity (please check all that apply)
☐ American Indian / Alaska Native ☐ Ashkenazi Jewish
☐ Asian ☐ Dutch
☐ Native Hawaiian or other Pacific Islander ☐ French Canadian
☐ Black/African American ☐ Hispanic/Latino
☐ White ☐ Sephardic Jewish
☐ Other, please specify _____ ☐ Other, please specify _____
- Are you currently participating in another mammogram study? Yes No
- What is the best phone number to reach you? _____
- What is the best day and time to reach you? _____

INCLUSION CRITERIA

- age 25 and older
- part of a HBOC family
- has a first degree relative with breast or ovarian cancer
- has not been diagnosed with breast cancer
- has not undergone a bilateral prophylactic mastectomy
- will report a due month for annual mammography, regardless of current compliance
- may be reached by telephone
- has received screening recommendations by mail from HCI in the past
- capable of providing informed consent
- not currently enrolled in another study involving screening mammography and will not enroll into such a study during enrollment in this study

STUDY FLOWCHART



STUDY DESIGN

A randomized, two-group study is proposed. One thousand four hundred and twenty-six women have been identified as being eligible for the study. All subjects will be asked to complete a pre-intervention assessment questionnaire in order to confirm eligibility and determine the due month for annual mammography. Subjects will be randomized to either the intervention or control group after informed consent and a HIPAA authorization is obtained. Subjects randomized to the intervention group will receive a reminder telephone call 60 days before their self-stated due month for mammography. Sixty days after the due month for mammography all subjects will receive a follow-up call to determine if a mammogram was obtained. A research assistant who has not been in contact with the subjects will conduct all telephone calls in order to simulate a real world scenario of a doctor's office or breast cancer center implementing a reminder telephone call strategy. Mammography frequency for each subject will be recorded. A Chi-square analysis will be conducted to determine if reminder telephone calls have a significant effect on mammography compliance in high-risk women. A validation of self-reported mammography will be done by obtaining mammography reports on a subset of women in each group.

RELEVANCE

Mammography has been proven to reduce breast cancer morbidity and mortality through early detection. Therefore, if a simple intervention such as a reminder telephone call can promote mammography compliance, thereby leading to early detection, more lives may be saved from this devastating disease.

This study is supported by the U.S. Army Medical Research and Materiel Command under Proposal No. BC031781.

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UNIVERSITY
Medical Center

EFFECT OF REMINDER TELEPHONE CALLS ON MAMMOGRAPHY COMPLIANCE IN HIGH-RISK WOMAN

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Abstract

Even though mammography has been proven to be effective in reducing breast cancer mortality this simple screening measure is underutilized by women in the general population as well as by women who are high-risk. The purpose of this randomized prospective study is to determine the effect of a simple reminder telephone call on mammography compliance in high-risk women. Evidence from eight of nine reviewed research studies conducted on women in the general population reported a significant increase in mammography compliance after a reminder telephone call was implemented. Women identified as being at high risk due to family history or the presence of a BRCA1 or BRCA2 genetic mutation are recommended to have annual mammography beginning at age 25 since their breast cancer risk approaches 85% and the cancer occurs much earlier. A reminder telephone call intervention has not been conducted in this high-risk population where the need for compliance is crucial. The hypothesis for this study is that a simple reminder telephone call will significantly increase mammography frequency in high-risk women compared to a control group. Subjects will be recruited from Creighton University's Hereditary Breast Cancer Resource of 472 families identified with hereditary breast ovarian cancer. Women who are at least 25 years old and have a first-degree relative diagnosed with breast or ovarian cancer will be invited to participate. A reminder telephone call will be conducted two months prior to the due month for mammography for women in the intervention group. Women in both groups will receive a follow-up telephone call two months after their reported due month for mammography. A Chi-square analysis will determine the effectiveness of reminder telephone calls in high-risk women. The implementation of a simple reminder telephone call may be conducted by advanced practice nurses working with high-risk women in order to increase mammography compliance thereby contributing to early detection and the best chance for a cure.

Introduction

Women who are part of a family with a hereditary breast ovarian cancer pattern and have a first degree relative with breast or ovarian cancer are at an increased risk for developing breast cancer 10-20 years earlier than women without a family history. It is vital these high-risk women follow the recommended screening measures of monthly self-breast examination, bi-annual clinical breast examination, and annual mammography. Even though mammography has been proven to decrease mortality and morbidity, women in the general population as well as high-risk women are still underutilizing it for early detection. Several intervention studies have been conducted in the general population to increase mammography compliance. Reminder telephone calls were found to be effective in those studies in increasing mammography compliance in women who are at the general population risk of 12%.

Hypothesis

A simple reminder telephone call will significantly increase mammography frequency in high-risk women compared to a control group of high-risk women who will not receive a reminder telephone call.

Specific Aims

- The specific aims of this study are:
- 1) to determine the effect of a reminder telephone call on mammography compliance in high-risk women;
 - 2) to train the candidate through mentoring and interdisciplinary collaboration how to conduct and analyze the findings of a randomized clinical research study to further her career in breast cancer research.

Pre-Intervention Assessment (PIA) Questionnaire

1. Have you ever had a mammogram? Yes No
 If you answered Yes:
 • how many have you had over the past 2 years? _____
 • what month of the year are they routinely due? _____

If you answered No:
 • do you plan to start having mammograms? Yes No
 • if so, which month would you routinely have them done? _____
 (Please indicate a month in order to be enrolled into the study.)

2. Have you ever had breast cancer? Yes No

3. Have you had one or both of your breasts removed either for cancer or for prevention? Yes No

4. Do you have health insurance? Yes No

5. Are you currently employed? Yes No
 Is Yes: Full-time? Part-time? (Please circle one.)

6. What best indicates your household income before taxes last year? (Optional)
☐ less than \$20,000 ☐ \$50,001 - \$75,000
☐ \$20,001 - \$35,000 ☐ over \$75,000
☐ \$35,001 - \$50,000

7. How much education have you completed?
☐ less than high school graduate ☐ college graduate
☐ high school graduate ☐ professional or postgraduate degree
☐ trade school or some college

8. Race (please check all that apply) Ethnicity (please check all that apply)
☐ American Indian / Alaska Native ☐ Ashkenazi Jewish
☐ Asian ☐ Dutch
☐ Native Hawaiian or other Pacific Islander ☐ French Canadian
☐ Black/African American ☐ Hispanic/Latino
☐ White ☐ Sephardic Jewish
☐ Other, please specify _____

9. Are you currently participating in another mammogram study? Yes No

10. What is the best phone number to reach you? _____

11. What is the best day and time to reach you? _____

Inclusion Criteria

age 25 and older
 part of a HBOC family
 has a first degree relative with breast or ovarian cancer
 has not been tested for BRCA1 or BRCA2 mutations
 has not been diagnosed with breast cancer
 has not undergone a bilateral prophylactic mastectomy
 will report a due month for annual mammography, regardless of current compliance
 may be reached by telephone
 has received screening recommendations by mail from HCI in the past
 capable of providing informed consent
 not currently enrolled in another study involving screening mammography and will not enroll into such a study during enrollment in this study

Study Design Flowchart

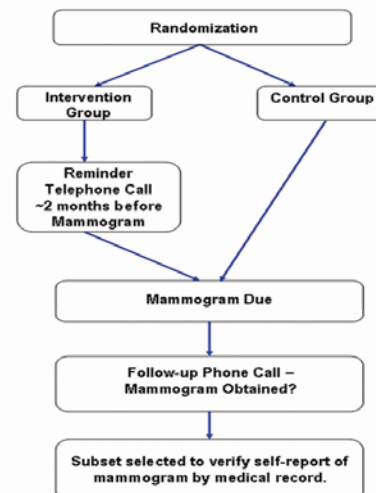


Table 1

Subjects who Responded (n = 428)	n
Randomized	32 (7%)
Reported Compliant	332 (76%)
Declined Participation	64 (15%)
No reason given	27
Prophylactic Bilateral Mastectomy	15
Breast Cancer	6
No Health Insurance	6

Table 2

Demographics of Randomized Subjects

Age (years)	43.6 (34-79)
Race (Caucasian)	100% (32/32)
Education Level (some college+)	84% (<high school graduate-postgraduate)
Have Health Insurance	94% (30/32)
Household Income (US\$)	35,001-50,000 (<25,000- >75,000)

Conclusion

Mammography has had an impact on the reduction of breast cancer morbidity and mortality through early detection. Therefore, if a simple intervention such as a simple reminder telephone call can significantly increase mammography compliance in high-risk women, thereby leading to early detection, more lives may be saved from this devastating disease.

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